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EXAMINER	
DUNSTON, JENNIFER ANN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/423,037	HEERY ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-22* is/are pending in the application.

4a) Of the above claim(s) *5,6 and 14-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,13 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendment, filed 6/26/2008, in which claim 1 was amended. Currently, claims 1 and 3-22 are pending.

Applicant's arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn. **This action is FINAL.**

Election/Restrictions

Applicant elected Group I, LXXLL, SRC-1 and oestrogen receptor species without traverse in the reply filed 11/13/2001.

Claims 14-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/2001.

Claims 5-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/2001.

Currently, claims 1, 3, 4 and 7-13 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4 and 7-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new rejection, necessitated by the amendment of claim 1 to include the limitation "provided that the fragment does not comprise a "NR box" sequence" in the reply filed 6/26/2008.

The claims encompass the provision of a first component which is an 8-10 amino acid fragment of a nuclear protein, wherein the fragment comprises only one signature motif B^1XXLL, in which B^1 is any natural hydrophobic amino acid, L is leucine, and X independently represents any natural amino acid, and the signature motif is a structural element of a nuclear protein that binds to a liganded nuclear receptor in the process of activating or repressing target genes, and the nuclear protein is a bridging factor responsible for an interaction between a liganded nuclear receptor transcription factor and a transcription initiation complex involved in the regulation of gene expression provided that the fragment does not comprise a "NR box" sequence. LXXLL is the elected species of signature motif. Accordingly, the claims encompass an 8-10 amino acid fragment of a nuclear protein that comprises LXXLL, which is not a "NR box."

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any

combination thereof. The specification defines the term "signature motif" to mean a short sequence which is the key structural element of a nuclear protein which binds to a liganded nuclear receptor as part of the process of the activation or repression of target genes (paragraph bridging pages 2-3). The specification describes the sequence LXXLL (SEQ ID NO: 1), which is found in SRC1 (e.g., page 4, lines 7-11). The specification describes the sequence as being capable of binding a nuclear receptor (liganded ER) and enhancing the transcriptional activity of the nuclear receptor (e.g., page 4, lines 7-11). The specification describes the presence of the LXXLL signature motif in TIF1, TIF2, p300, RIP 140 and the TRIP proteins (e.g., page 4, lines 11-13). The specification recognizes that Le Douarin et al (EMBO Journal, Vol. 15, pages 6701-6715, 1996, of record) identified a leucine rich region in three coactivators, TIF1, RIP 140, and TRIP3 (e.g., page 1, lines 24-25). The specification notes that Le Douarin et al refer the leucine rich region as the "NR box" (e.g., page 1, lines 24-25).

Le Douarin et al teach that nuclear receptors (NR) contain a region known as the AF-2 activating domain (AD) core, which is highly conserved and present in all known transcriptionally active members of the NR superfamily (e.g., page 6701, paragraph bridging columns). Several proteins interact with the AF-2-containing ligand binding domain (LBD) of several NRs (steroid, thyroid, vitamin D3 and retinoid receptors) in the presence of agonistic ligands but not in the presence of antagonists; these interacting proteins include RIP140, TIF1, Trip/SUG1, SRC-1/p160, CBP and TIF2/Grip1 (e.g., paragraph bridging pages 6701-6702). Le Douarin et al teach the fusion of various TIF1 mutants to the ER DBD to map the regions required for interaction with retinoid X receptor (RXR) (e.g., pages 6701-6705, NRs and the mouse HP1 homologues interact with two adjacent but distinct domains of TIF1). Le Douarin et

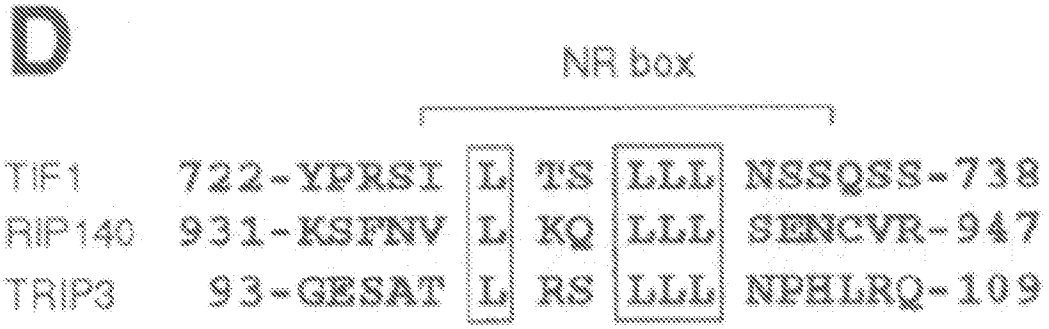
al identify a minimal RXR-interacting domain in TIF1, which mapped between residues 723 and 735 of TIF1 (e.g., page 6705, left column, 1st paragraph; Figure 3). The 10 amino acid sequence LLTSLLLNSS was shown to specifically interact with RXR, whereas mutation to LLTSELLNSS or LLTSAALNSS abolished the interaction (e.g., page 6705, left column, 1st paragraph; Figure 3A). This interaction requires the AF-2 region of RXR (e.g., page 6705, left column, 1st paragraph; Figure 3). Le Douarin et al conclude that TIF1 contains a 10 amino acid long sequence that is sufficient on its own to functionally interact with NRs in both a ligand- and AF-2-dependent manner, and similar sequences are present in RIP140 and TRIP3 (e.g., page 6705, left column, 1st paragraph). Le Douarin et al demonstrate that the conserved 10 amino acid sequence, referred to as an NR box, is sufficient to interact with RAR and ER, whether the NR box is obtained from TIF1 or RIP140 (e.g., Figure 3B).

The specification asserts that Le Douarin et al did not disclose a signature motif within the meaning of the present invention, because the NR box within the meaning of Le Douarin would be present in at most only 4 of the 39 signature motifs identified by the present invention in Figures 3A and 4 (e.g., page 8, lines 3-6). However, the "NR box" of Le Douarin et al is "signature motif" within the meaning of the claims, because it is a short sequence which is the key structural element of a nuclear protein which binds to a liganded nuclear receptor as part of the process of the activation or repression of target genes.

The specification describes Figure 3A as an alignment of LXXLL motif sequences present in human RIP 140, human SRC1a, mouse TIF2, mouse CBP, p300, mouse TIF1, and human TRIP proteins (e.g., specification, page 11, lines 13-17). The specification asserts that the LXXLL motif sequences of the present specification are not "NR boxes" as disclosed by Le

Douarin et al. However, comparison of the sequences disclosed in Figure 3A to the "NR boxes" of Le Douarin et al indicates that some of the sequences are identical. Figure 3A discloses the following LXXLL motif sequence for TIF1:

where the amino acids enclosed by the lines are boxed in the figure to indicate the presence of the LXXLL motif. Le Douarin et al teach the same sequence in Figure 1D:



where the LXXLLL motif is boxed. Further, the specific sequence used in the two-hybrid assay of Le Douarin et al is the 10 amino acid sequence ILTSLLLNSS, which is identical to the 10 amino acid sequence ILTSLLLNSS identified in Figure 3A of the specification. The sequences disclosed by Le Douarin et al for RIP140 and TRIP3 are also present in Figure 3A of the specification. Each of these sequences contains 8-10 amino acids which are identical and function as a "signature motif." Identical sequences are the same regardless of whether the prior art calls them a "NR box" or the instant specification calls them not an "NR box".

The art teaches that the NR binding motif LXXLL is called an NR box (Ding et al. Molecular Endocrinology, Vol. 12, pages 302-313, February 1998, cited on the IDS filed

2/23/2000; e.g., Abstract; Figure 1A; Galande et al. Chembiochem, Vol. 6, pages 1991-1998, 2005; e.g., Abstract; paragraph bridging pages 1991-1992). Accordingly, the art teaches that the NR box is the LXXLL motif. The claims are specifically drawn to peptides comprising the LXXLL motif (elected species). However, the claims require the LXXLL motif to not be an "NR box." The specification does not describe sequences that are not NR boxes but contain the LXXLL motif and function as claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of LXXLL motifs that are not NR boxes, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

Given that the art teaches the LXXLL motif is an NR box and functions as a signature motif in that it is a short sequence which is the key structural element of a nuclear protein which binds to a liganded nuclear receptor as part of the process of the activation or repression of target

genes, all of the sequences disclosed in the specification are NR boxes. Therefore, the specification does not describe sequences that meet the structural and functional limitations of the claims but do not contain an "NR box." Therefore, the skilled artisan would have reasonably concluded applicants were not in possession of the claimed invention for claims 1, 3, 4 and 7-13.

Claims 1, 3, 4 and 7-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method where the signature motif LXXLL is an NR box, does not reasonably provide enablement for the method where the signature motif is not an NR box. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This is a new rejection, necessitated by the amendment of claim 1 to include the limitation "provided that the fragment does not comprise a "NR box" sequence" in the reply filed 6/26/2008.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The claims are drawn to a method for identifying an inhibitor compound capable of reducing the interaction between a first component and a second component, comprising the steps of a) placing in contact: i) a potential inhibitor compound; ii) a first component, and iii) a second component; and b) detecting the presence or absence of

inhibition between the interaction of i) and ii). The claims define the first component as comprising an 8-10 amino acid fragment of a nuclear protein, wherein the fragment comprises only one signature motif B^1XXLL, in which B^1 is any natural hydrophobic amino acid, L is leucine, and X independently represents any natural amino acid, and the signature motif is a structural element of a nuclear protein that binds to a liganded nuclear receptor in the process of activating or repressing target genes, and the nuclear protein is a bridging factor responsible for an interaction between a liganded nuclear receptor transcription factor and a transcription initiation complex involved in regulation of gene expression provided that the fragment does not comprise an NR box sequence. The elected species of signature motif is LXXLL. The elected species of nuclear protein is SRC-1, and the elected species of nuclear receptor is estrogen receptor.

The nature of the invention is complex in that the first component must comprise the LXXLL sequence from a nuclear protein such as SRC-1, RIP 140, TIF1, or TRIP3, for example, and must not be a "NR box."

Breadth of the claims: The claims are narrowly drawn with respect to the first component. The first component must comprise the LXXLL sequence from a nuclear protein such as SRC-1, RIP 140, TIF1, or TRIP3, for example, and must not be a "NR box."

Guidance of the specification and existence of working examples: The specification defines the term “signature motif” to mean a short sequence which is the key structural element of a nuclear protein which binds to a liganded nuclear receptor as part of the process of the activation or repression of target genes (paragraph bridging pages 2-3). The specification describes the sequence LXXLL (SEQ ID NO: 1), which is found in SRC1 (e.g., page 4, lines 7-

11). The specification describes the sequence as being capable of binding a nuclear receptor (liganded ER) and enhancing the transcriptional activity of the nuclear receptor (e.g., page 4, lines 7-11). The specification describes the presence of the LXXLL signature motif in TIF1, TIF2, p300, RIP 140 and the TRIP proteins (e.g., page 4, lines 11-13). The specification recognizes that Le Douarin et al (EMBO Journal, Vol. 15, pages 6701-6715, 1996, of record) identified a leucine rich region in three coactivators, TIF1, RIP 140, and TRIP3 (e.g., page 1, lines 24-25). The specification notes that Le Douarin et al refer the leucine rich region as the "NR box" (e.g., page 1, lines 24-25). The specification describes Figure 3A as an alignment of LXXLL motif sequences present in human RIP 140, human SRC1a, mouse TIF2, mouse CBP, p300, mouse TIF1, and human TRIP proteins (e.g., specification, page 11, lines 13-17). The specification asserts that the LXXLL motif sequences of the present specification are not "NR boxes" as disclosed by Le Douarin et al. The specification describes Figure 3A as an alignment of LXXLL motif sequences present in human RIP 140, human SRC1a, mouse TIF2, mouse CBP, p300, mouse TIF1, and human TRIP proteins (e.g., specification, page 11, lines 13-17).

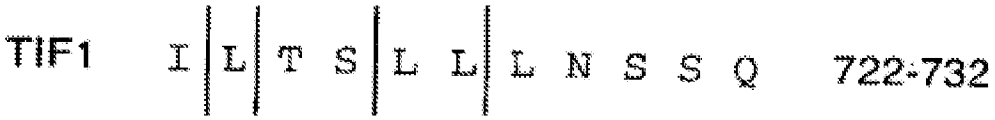
Predictability and state of the art: Le Douarin et al teach that nuclear receptors (NR) contain a region known as the AF-2 activating domain (AD) core, which is highly conserved and present in all known transcriptionally active members of the NR superfamily (e.g., page 6701, paragraph bridging columns). Several proteins interact with the AF-2-containing ligand binding domain (LBD) of several NRs (steroid, thyroid, vitamin D3 and retinoid receptors) in the presence of agonistic ligands but not in the presence of antagonists; these interacting proteins include RIP140, TIF1, Trip/SUG1, SRC-1/p160, CBP and TIF2/Grip1 (e.g., paragraph bridging pages 6701-6702). Le Douarin et al teach the fusion of various TIF1 mutants to the ER DBD to

map the regions required for interaction with retinoid X receptor (RXR) (e.g., pages 6701-6705, NRs and the mouse HP1 homologues interact with two adjacent but distinct domains of TIF1). Le Douarin et al identify a minimal RXR-interacting domain in TIF1, which mapped between residues 723 and 735 of TIF1 (e.g., page 6705, left column, 1st paragraph; Figure 3). The 10 amino acid sequence L**L**TS**LLL**NSS was shown to specifically interact with RXR, whereas mutation to L**L**TS<u>E</u>**LL**NSS or L**L**TS<u>AA</u>**L**NSS abolished the interaction (e.g., page 6705, left column, 1st paragraph; Figure 3A). This interaction requires the AF-2 region of RXR (e.g., page 6705, left column, 1st paragraph; Figure 3). Le Douarin et al conclude that TIF1 contains a 10 amino acid long sequence that is sufficient on its own to functionally interact with NRs in both a ligand- and AF-2-dependent manner, and similar sequences are present in RIP140 and TRIP3 (e.g., page 6705, left column, 1st paragraph). Le Douarin et al demonstrate that the conserved 10 amino acid sequence, referred to as an NR box, is sufficient to interact with RAR and ER, whether the NR box is obtained from TIF1 or RIP140 (e.g., Figure 3B).

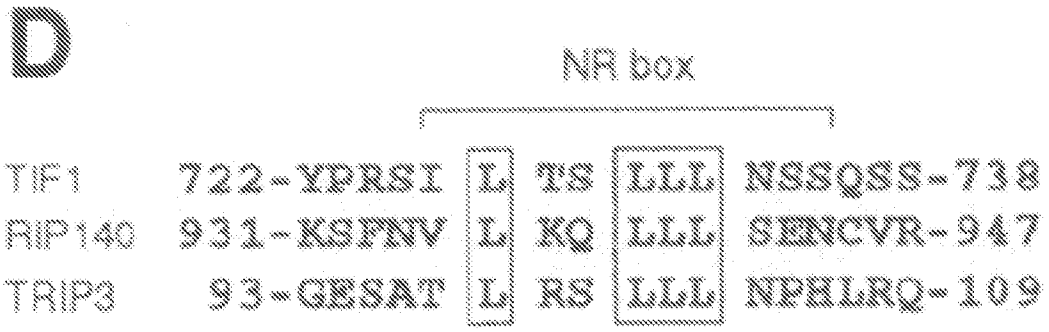
The specification asserts that Le Douarin et al did not disclose a signature motif within the meaning of the present invention, because the NR box within the meaning of Le Douarin would be present in at most only 4 of the 39 signature motifs identified by the present invention in Figures 3A and 4 (e.g., page 8, lines 3-6). However, the "NR box" of Le Douarin et al is "signature motif" within the meaning of the claims, because it is a short sequence which is the key structural element of a nuclear protein which binds to a liganded nuclear receptor as part of the process of the activation or repression of target genes.

The specification describes Figure 3A as an alignment of LXXLL motif sequences present in human RIP 140, human SRC1a, mouse TIF2, mouse CBP, p300, mouse TIF1, and

human TRIP proteins (e.g., specification, page 11, lines 13-17). The specification asserts that the LXXLL motif sequences of the present specification are not "NR boxes" as disclosed by Le Douarin et al. However, comparison of the sequences disclosed in Figure 3A to the "NR boxes" of Le Douarin et al indicates that some of the sequences are identical. Figure 3A discloses the following LXXLL motif sequence for TIF1:



where the amino acids enclosed by the lines are boxed in the figure to indicate the presence of the LXXLL motif. Le Douarin et al teach the same sequence in Figure 1D:



where the LXXLLL motif is boxed. Further, the specific sequence used in the two-hybrid assay of Le Douarin et al is the 10 amino acid sequence ILTSLLLNSS, which is identical to the 10 amino acid sequence ILTSLLLNSS identified in Figure 3A of the specification. The sequences disclosed by Le Douarin et al for RIP140 and TRIP3 are also present in Figure 3A of the specification. Each of these sequences contains 8-10 amino acids which are identical and function as a "signature motif." Identical sequences are the same regardless of whether the prior art calls them a "NR box" or the instant specification calls them not an "NR box".

The art teaches that the NR binding motif LXXLL is called an NR box (Ding et al. Molecular Endocrinology, Vol. 12, pages 302-313, February 1998, cited on the IDS filed 2/23/2000; e.g., Abstract; Figure 1A; Galande et al. Chembiochem, Vol. 6, pages 1991-1998, 2005; e.g., Abstract; paragraph bridging pages 1991-1992). Accordingly, the art teaches that the NR box is the LXXLL motif. The claims are specifically drawn to peptides comprising the LXXLL motif (elected species). However, the claims require the LXXLL motif to not be an "NR box." The specification does not teach sequences that are not NR boxes but contain the LXXLL motif and function as claimed.

Amount of experimentation necessary: The claims encompass the use of a genus of signature motifs that comprise the LXXLL motif but are not NR boxes. The claims encompass the use of this genus, which is defined as containing the LXXLL motif (elected species), which functions to bind to a liganded nuclear receptor in the process of activating or repressing target genes. Further, the claims require the motif to be from a nuclear protein that is a bridging factor responsible for an interaction between a liganded nuclear receptor transcription factor and a transcription initiation complex involved in regulation of gene expression. However, the art teaches that the LXXLL motif is an NR box found in nuclear proteins that act as bridging factors in the manner discussed above. Therefore, one would not know how to make a first component that is a signature motif within the meaning of the claims where it is not an NR box. It would require undue experimentation to identify first components such that one could make the components and use them in the claimed assay.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an

undue amount of experimentation to make and/or use the claimed invention. Therefore, claims 1, 3, 4 and 7-13 are not considered to be fully enabled by the instant specification.

Response to Arguments - 35 USC § 103

The rejection of claims 1, 3, 4, 7 and 9-12 under 35 U.S.C. 103(a) as being unpatentable over Le Douarin et al in view of Scanlan et al has been withdrawn in view of Applicant's amendment to the claims in the reply filed 6/26/2008. The references do not teach the signature motif that is not an NR box.

The rejection of claims 1, 3, 4, 7 and 9-13 under 35 U.S.C. 103(a) as being unpatentable over Le Douarin et al in view of Dedhar has been withdrawn in view of Applicant's amendment to the claims in the reply filed 6/26/2008. The references do not teach the signature motif that is not an NR box.

The rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over Le Douarin et al in view of Dedhar, Collingswood et al and Spencer et al has been withdrawn in view of Applicant's amendment to the claims in the reply filed 6/26/2008. The references do not teach the signature motif that is not an NR box.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

/JD/

/Celine X Qian Ph.D./
Primary Examiner, Art Unit 1636